



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

m3064m

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4380

July 20, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Balkema, World Wide President
Bayer Corporation Consumer Care Division
36 Columbia Road
Morristown, NJ 07460

Dear Mr. Balkema:

From April 4 through April 25, 2000, Food and Drug Administration (FDA) Investigator David J. Hafner conducted an inspection of Bayer Corporation Consumer Care Division, located in Myerstown, Pennsylvania. During this inspection deviations from Current Good Manufacturing Practices (CGMP) regulations codified as Title 21 Code of Federal Regulations (21 CFR) Part 211 were documented. The following deviation causes your drug product, Cipro HC Otic Suspension, to be adulterated within the meaning of Section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act (the Act).

Failure to conduct a thorough investigation of an unexplained discrepancy or the failure of a batch or any of its components to meet its specifications or extend the investigation to other batches that may have been associated with the specific failure or discrepancy [21 CFR 211.192]. For example, no investigation was extended to lots of Cipro HC Otic Suspension manufactured with benzyl alcohol, lot [REDACTED] which failed its [REDACTED] and [REDACTED] specification and benzyl alcohol, lot [REDACTED], which failed its [REDACTED] specification. Benzyl alcohol, used as a preservative, is a component of Cipro HC Otic Suspension.

The above is not intended to be an all-inclusive list of deficiencies that exist at your firm. FDA inspections are audits which are not intended to determine all deviations from CGMPs. It is not the role of FDA to inspect a firm into compliance. As top management, it is your responsibility to ensure that all requirements of the CGMP regulations are being met as well as all other requirements of the Act. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

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Warning Letter: Bayer Corporation Consumer Care Division

We are in receipt of a letter dated May 24, 2000 from John O'Neill, V.P. Manufacturing, in response to the form FDA-483, issued at the conclusion of the April 2000 inspection of your firm. Your responses to observations #2 and #3 of the form FDA-483 are inadequate because they address only a review of the release data for the Cipro HC Otic Suspension lots manufactured with the referenced lots of benzyl alcohol. Long term assessment of the preservative effectiveness of benzyl alcohol in lots Cipro HC Otic Suspension which may have been affected by the referenced lots of benzyl alcohol was not addressed.

You should take prompt action to correct the deviations with respect to all products where these deficiencies in controls apply. Failure to promptly take corrective action may result in regulatory action without further notice. Possible regulatory actions include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Additionally, new drug applications (NDA's), abbreviated new drug applications (ANDA's), and export approval requests may not be approved until the aforementioned violations are corrected.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to any additional specific actions you have taken or intend to take to correct these violations and prevent their recurrence. Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the address referenced above.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District